From: "JMCARLBERG" <JMCARLBERG@aol.com>, on 1/19/98 9:08 PM:
To: George Mitchell@OD@FDACVM

January 19, 1998
FDA's Dockets Management Branch (HFA-305)
12420 Parklawn Dr.
Room 1-23
Rockville, MD 20857

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Re: Proposal to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses

Docket No. 97N-0217

Dear Sir or Madam:

The purpose of this letter is to offer our comments on the proposed change in legislative and regulatory policy regarding the use of drugs and chemical in minor species. As a major producer of food fish in aquaculture, this matteris extremely important to the future production capabilities of our company and for the entire U.S. warmwater fish culture industry. Kent SeaFarms was the first and is the largest producer of hybrid striped bassin the United States. The principals of our company have extensive scientific and technical backgrounds, having conducted aquaculture research for 10 years at San Diego State University and Scripps Institution of Oceanography. For the past 20 years we have continued our research activities to develop new and innovative technologies to improve aquaculture production of striped bass at our farms and for the industry as a whole. We are extremely familiar with the needs of the industry and have participated as founder and past President of the Striped Bass Growers Association, member of the Board of Directors of the National Aquaculture Association, and World Aquaculture Society. The sources of wild fishery products available from the capture fisheries is finite and most of the seafood resources in the U.S. are fully exploited. Aquaculture is an exciting and very viable method to supplement these supplies to provide wholesome and nutritious seafood to the growing U.S. population as well as worldwide. Increased production also will help reduce the $3 billion trade deficit in seafood. To accomplish this goal, it will be necessary to develop better technologies and improved production methods to compete with imports of products from foreign countries having major water resources and often with few limitations on the use of drugs and chemicals in their animal production industries. We need to have access to effective chemicals to control parasites and on occasion we need the use of antibiotics in feeds to treat bacterial diseases. It has been our experience that it is difficult to attract the support and assistance from pharmaceutical firms to develop the required information to register drugs for use in aquaculture. The industry is relatively small the potential market will not provide a reasonable return on their financial investment. This fledgling industry needs to be considered a part of the animal food industry. Drugs approved for other animals need to be approved for fish through the use of "extralable" or with the authorization of a licensed veterinarian under provision in the Veterinarian Feed Directive. When registration is achieved for one species of fish, other species should be approved with relatively few field efficacy trials, and pivotal laboratory studies to determine animal safety, dose, withdrawal, and residue limits. We are pleased to see the initiative taken by the FDA/CVM

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to facilitate the use of drugs and chemicals to stop the needless death of animals and to provide a beneficial tool to control diseases in animal food production. We encourage your efforts to establish a Minor Use Animal Drug Program to expand the provisions for extralabel use, remove financial disincentives to drug sponsors, and to improve the approval process and share test data between species groups. Thank you for the opportunity to respond to your proposal and we look forward to working with FDA on this matter in the future.

Sincerely,
James M. Carlberg
President